Remarks

Claims 59, 61-66, 68-78, 100-115 are now in the case. Claims 79-99 have been cancelled. Claims 59, 66 and 100 have been amended. Support for the amended claims can be found throughout the specification, see in particular page 12, lines 20-21, figures 1, 2 and 4 and examples 4 and 5.

Rejection under U.S.C. 112, first paragraph (New Matter)

Claims 112 and 114 are rejected under 35 U.S.C. §112, first paragraph, as being considered to contain matter that was not described in the specification. Applicants respectfully traverse these grounds for rejection.

Support for claims 112 and 114 can be found in the specification, see particularly page 5. "Accordingly, the mature polypeptide comprises an amino acid sequence starting at an amino acid between, and including, residue 51 and 58 (*e.g.*, at amino acid 51, 52, 53, 54, 55, 56, 57, or 58) of SEQ ID Nos: 6, 12, and 31." (See page 5, lines 5-6). These amino acid residues mark the beginning of the mature polypeptide sequence. Such polypeptide sequences as those claimed in claims 112 and 114 are mature nectin-3α and β polypeptides.

"The transmembrane domain of nectin-3α is predicted to include the amino acids from about amino acid 405 through amino acid 424 of SEQ ID NO:6" (See page 5, lines 17-18). "The transmembrane domain of nectin-3β and γ is predicted to include the amino acids approximately from amino acid 366 through amino acid 385 of SEQ ID NO: 12 or 31, respectively" (See page 5, lines 20-22). These amino acid residues mark the end of the extracellular domain. Such polypeptide sequences as those claimed in claims 112 and 114, terminated at such amino acid residues are mature soluble polypeptides nectin-3α and β polypeptides.

"The nectin-3α and β forms have intracellular C-terminal domains of similar size but different overall amino acid sequence (approximately amino acids 425 through 549 of SEQ ID NO:6 and approximately amino acids 386 through 510 of SEQ ID NO:12, respectively)" (See page 5, lines 25-27). These amino acid residues mark the end of the cytoplasmic domain. Such polypeptide sequences as those claimed in claim 112 and 114, terminated at such amino acid residues are mature membrane-bound forms of the nectin-3α and β polypeptides.

Claims 112 and 114 find support in the specification and more particularly point out and distinctly claim Applicants' invention as described in the specification at the time of filing and therefore do not constitute new matter.

Applicants respectfully submit that for at least the reasons stated above, the rejection of claims 112 and 114 under 35 U.S.C. §112, first paragraph (New Matter), has been overcome and withdrawal of the rejection is respectfully requested.

Rejection under U.S.C. 112, first paragraph (Enablement)

Claims 59, 61-66, 68-112 and 114 stand rejected under U.S.C. § 112, first paragraph, allegedly because the specification is not enabling. Applicants respectfully traverse these grounds for rejection.

In the paragraph bridging pages 2 and 3 of the above cited Office Action, the US Patent and Trademark Office, ("Office") states that the specification "does not reasonably provide enablement for any substantially purified polypeptide comprising amino acids 58-404 of SEQ ID NO: 4 or 6, in claim 59, wherein said polypeptide comprises any amino acid sequence extending from amino acid 58 through the C-terminus of SEQ ID NO:2 or 6, 13, 15 in claim 60...wherein the polypeptide comprises any amino acid sequence extending from amino acid 58 through the C-terminus of SEQ ID NO: 10, 12, 14, 16 and 31 in claim 67".

Claims 60 and 67 were cancelled in the response dated August 18, 2005, and are no longer part of the claim set under examination.

As indicated above, claims 59 and 66 have been amended and claims 79-100 have been cancelled. Applicants reserve the right to pursue the cancelled matter in continuation applications. The Office once again acknowledges the enablement of Applicants' invention, see page 4, first full paragraph: "SEQ ID NO: 13 used in examples 4-6 is enabled. Further, the previous Office Action states that the sequences comprising the complete signal sequences (i.e., SEQ ID NOs: 6 and 10), signal sequences lacking N-terminal amino acid residues (SEQ ID NOs: 2 and 8), signal sequences with murine substituted sequences (i.e., SEQ ID NOs: 4 and 10), transmembrane domains, cytoplasmic domains, Fc regions from human IgG1 (i.e., SEQ ID NOs: 13 and 14), and small peptide affinity tags such as FLAG and His tags (i.e., SEQ ID NOs: 15 and 16) are enabled."

All that is required of §112, first paragraph, is that there be some way to make and use the claimed subject matter. The Office has repeatedly acknowledged the of enablement of numerous and varied sequences within the scope of the claimed invention. In the absence of some reason or evidence showing why one of skill in the art would not find the claimed invention enabled, in spite of the acknowledgment of enablement by the Office, Applicants respectfully submit that they have met their burden and that the rejection is unfounded.

Applicants respectfully submit that for at least the reasons stated above, the rejection of claims 59-111 under 35 U.S.C. §112, first paragraph (enablement), has been overcome and withdrawal of the rejection is respectfully requested.

Rejection under U.S.C. 112, first paragraph (Written Description)

Claims 59, 61-66, 68-78, 112 and 114 are rejected under U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse these grounds for rejection.

In the paragraph bridging pages 6 and 7, the Office states "Applicant is not in possession of any substantially purified polypeptide comprising amino acids 58-404 of SEQ ID NO: 4 or 6, in claim 59, wherein said polypeptide comprises any amino acid sequence extending from amino acid 58 through the C-terminus of SEQ ID NO:2 or 6, 13, 15 in claim 60...wherein the polypeptide comprises any amino acid sequence extending from amino acid 58 through the C-terminus of SEQ ID NO: 10, 12, 14, 16 and 31 in claim 67".

As mentioned above, claims 60 and 67 were cancelled in the response dated August 18, 2005, and are no longer part of the claim set under examination, as is indicated in the claim set above.

On page 7 of the above identified Office Action, in the sixth paragraph, the Office states, "however the functional correlation or relationship between the structure of the invention, the core structure of nectin 3 (amino acids 58-404 or SEQ ID NOs: 4 or 6) and its inhibition of endothelial cell migration function is not claimed." (emphasis added). The Office also states in the final paragraph on page 7, "[h]owever, no correlation or relationship between the structure of the invention, the core structure of nectin 3 (aa58-404 of SEQ ID NOs:4 or 6) and it's inhibition of endothelial cell migration is claimed for the skilled artisan to envisage the claimed genus of polypeptides comprising said core structure of nectin 3 which retains the features essential to the instant invention." (emphasis added)

> A genus may be described via "recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." (University of California v Eli Lilly and Co., 119 F.3d 1559, 1569) (Lilly). Such a description can take the form of "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with known or disclosed correlation between function and structure, or some combination of such characteristics." (Guidelines for Examination of Patent Applications under

35 U.S.C. §112, First Paragraph (Written Description) Requirement, 66 Fed. Reg. 1099, at 1106) (Guidelines). (emphasis added)

The Examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an Applicant's disclosure a description a description of the invention defined in the claims (In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The Office provides no evidence or reasoning for its assertion that to meet the requirements for written description under U.S.C 112, first paragraph, a correlation or relationship must be claimed, not described, for the skilled artisan to envision the genus.

More importantly, the Action provides no evidence or reasoning to dispute Applicants previous assertion that the description in the specification supporting the claimed invention meets the requirements of Lilly and exceeds the requirements necessary to describe the structural features common to the members of the claimed genus, as stated in the Guideline. In support of this assertion, Applicants point to description of:

(a) complete and/or partial structure, such as polypeptides comprising amino acid residues 58-404 of SEQ ID NOs:4 or 6 (which include residues 74-365 of SEQ ID NOs: 10, 12 and 31) as well and the complete structure of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 15, 16 and 31, and additionally the soluble polypeptides comprising amino acid residues 58-404 or amino acid residues 58-366 as disclosed in SEQ ID NOs: 13 and 14;

(b) physical properties, such as extracellular, transmembrane and cytoplasmic domains of SEQ ID NO:2, 4, 6, 8, 10, 12, and 31; and

(c) functional characteristics coupled with known or disclosed correlation between function and structure, such as the association of polypeptides comprising amino acid residues 58-404 of SEQ ID NOs: 4 or 6 with inhibition of cell migration.

Applicants' recitation comes in the form of not only a description of complete and/or partial structures, but also identification of physical properties and functional characteristics coupled with known or disclosed correlations between the function and structure of the polypeptides of this genus. These features constitute a substantial portion of the genus and meet the requirements as defined in both Lilly and the Guidelines.

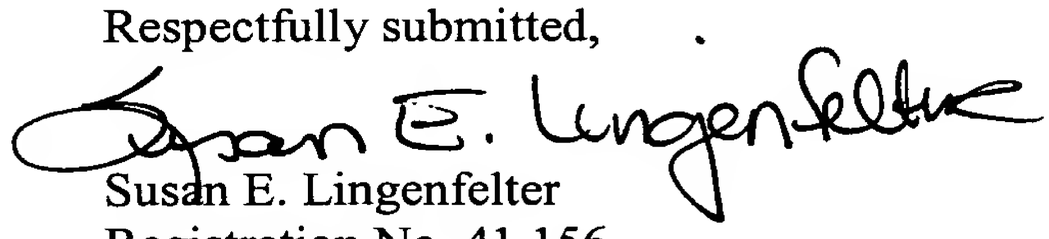
However, merely to advance the claims towards allowance, claims 59 and 66 have been amended to recite inhibition of endothelial cell migration.

Applicants respectfully submit that for at least the reasons stated above, the rejection of claims 59, 61-66, 68-78, 112 and 114 under 35 U.S.C. §112, first paragraph (written description), has been overcome and withdrawal of the rejection is respectfully requested.

CONCLUSION

Applicants submit that the presented claims are in condition for allowance. A favorable action is earnestly requested. Applicants' attorney invites the Examiner to call her at the number below if any issue remains outstanding.

Respectfully submitted,



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